REMARKS

This Preliminary Amendment is submitted with a Request for Continued Examination (RCE) filed this date. Claims 1-21 are pending in this application. All claims presently stand rejected.

In the final Office Action filed in the parent application, claims 1-2, 4-5, 10-13 and 15-20 were rejected under 35 U.S.C. 103(a) over U.S. Patent No. 5,792,124 to Horrigan, et al, ("Horrigan") in view of U.S. Patent No. 6,159,187 to Park et al ("Park"). Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan in view of Park as applied to claim 1, and further in view of U.S. Patent No. 5,380,304 to Parker ("Parker"). Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of U.S. Patent No. 5,599,325 to Ju, et al. ("Ju"). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of U.S. Patent No. 6,210,396 to MacDonald, et al. ("MacDonald").

According to the Examiner, Horrigan discloses a catheter or sheath having certain features in common with the claimed invention. The Examiner acknowledged, however, that Horrigan does not teach a key element of the present invention, namely the use of a coil as a reinforcement means. Park was cited for its teaching of a catheter section having a "braided wire coil", as shown in Fig. 7. Thus, according to the Examiner, it would have been obvious to have substituted a "braided wire coil" as disclosed by Park for the wire braid of Horrigan. As stated by the Examiner, "The sheath of the combination of Horrigan et al and Park et al is inherently kink resistant due to the presence of reinforcement in the form of a braided wire coil and inherently flexible since it is made of polymer." OA mailed June 29, 2004, page 3.

The present invention is directed to a flexible, kink resistant introducer sheath. It is desirable to construct an introducer sheath that is both flexible and resistant to kinking. It is desirable to construct an introducer sheath in a manner such that it can be readily advanced through tortuous body passageways and/or directed to sensitive treatment sites deep within the vasculature of a patient. If a sheath kinks as it is traversing these passageways, it generally becomes un-useable and must be replaced with a new sheath. This adds unnecessary cost to the

procedure, and increases the level of difficulty of the procedure. It also increases the amount of time required to complete the procedure, if it can be completed at all.

As a sheath is advanced through tortuous body passageways, it is desirable that the sheath be able to maintain all, or at least most, of its generally circular cross-section through as large a bending angle as possible. As long as the cross-section of the sheath remains substantially intact, the physician can deliver the largest possible medical interventional device, such as a stent, through the sheath to a selected site of the body passageway. Providing a coil-reinforced sheath enables the physician to negotiate tight bends in the vasculature that often cannot be negotiated with sheaths that are not equipped with this type of reinforcement. As a result, an interventional device that has an outer diameter nearly as large as the inner diameter of a sheath can be passed through the sheath even after the sheath has been bent through a wide bending angle.

As further support for the contentions presented herein and the present claims, the Assignee of the present applicant, namely Cook Incorporated ("Cook"), provides herein the Declarations of David Barnes, General Manager of ABAQUS Central, Inc., ("ABAQUS") of Lafayette, Indiana, and Gary Roubin, M.D., Ph.D. The Barnes Declaration is attached hereto as Exhibit 1, and the Roubin Declaration is attached hereto as Exhibit 2.

As stated in the Barnes Declaration, ABAQUS utilizes the ABAQUS computer program to perform Finite Element Analysis ("FEA") services on a contract basis for its customers. FEA is a technique that allows engineers to simulate the physical behavior of engineered products using a computer, and to minimize the number of physical prototype tests required during development of their products. FEA also provides a vehicle to enable engineers to gain deeper understanding into the physics of their products than can be gained by physical testing alone. In the medical industry, the ABAQUS program is commonly used to simulate stents, catheters, and other interventional medical devices. Barnes Declaration, paragraph 6.

ABAQUS was asked by Cook to examine Cook's United States Patent Application Serial No. 09/815,567 ("the '567 application"), the prosecution history of the '567 application, and the prior art references cited by the Examiner during the prosecution of the '567 application, most notably, the primary Horrigan reference. ABAQUS was asked to construct a computer FEA model of a braid-reinforced catheter constructed according to the teachings of the Horrigan

patent. ABAQUS was also asked to construct a computer FEA model of another reinforced catheter constructed according to the teachings of the Horrigan patent and identical to the Horrigan braid-reinforced catheter, except that in this instance a coil reinforcement was substituted for the braid. Finally, ABAQUS was asked to construct a third computer FEA model of a catheter constructed according to the teachings of Horrigan that was otherwise identical to the braid- and coil-reinforced catheters, except that in this instance no reinforcement was included in this catheter model. Barnes Declaration, paragraph 12.

The models created by ABAQUS were subjected to FEA analysis wherein the models were bent to progressively larger bend angles. This bending was intended to simulate the behavior of these sheaths to the type of severe bending that may occur during introduction of a sheath into the vasculature. A graphic depiction of the results from the three simulation tests is attached to the Barnes Declaration as Exhibits A, B and C. A brief explanation of the significance of these simulation tests is provided below. Mr. Barnes' interpretation of the tests is provided at paragraphs 17-21 of his Declaration.

Barnes' Exhibit A illustrates the results of an analysis wherein the displacement behavior of a braid-reinforced sheath was compared to that of a coil-reinforced sheath when each sheath was bent to the same total bend angle of about 45 degrees per 10 mm length sheath segment. The braid-reinforced sheath is indicated at the right of the page, and the coil-reinforced sheath is indicated at the left. As illustrated, the coil-reinforced sheath has not kinked at the angle shown, whereas the braid-reinforced sheath has kinked severely.

Barnes' Exhibit B illustrates the results of an analysis wherein the resistance to bending of the three sheath models described above was compared as the bending angle was increased. As shown in the plot of Exhibit B, the un-reinforced sheath kinks at a radius of curvature of about 29 mm, and the braid-reinforced sheath kinks at a radius of curvature of about 15 mm. The coil-reinforced sheath does not kink until it reaches a radius of curvature of about 11 mm. A difference of this magnitude in the radius of curvature needed to form a kink is significant, particularly to the medical practitioner who desires to insert a sheath through a tortuous passageway in the vasculature, and to maintain sufficient cross-section of the sheath to introduce an interventional device through the interior of the sheath.

Barnes' Exhibit C illustrates the results of an analysis wherein the minor-to-major diameter ratio of the cross-section of each of the three simulated sheaths were compared along a defined bending operation. A diameter ratio of 1.0 means the cross-section is circular (both diameters are the same), while a diameter ratio of 0.0 means the cross section has totally collapsed and the opposing walls of the minor diameter are touching each other. This plot shows that the cross-section of the coil-reinforced sheath maintains the "most circular" cross-section (i.e, having a diameter ratio closest to 1.0) throughout the largest bending angle. Furthermore, the plots also show that the coil-reinforced sheath maintains a more constant cross-sectional ratio of around 0.9 over a much wider bend angle range than the other two. For purposes of comparision, even before kinking occurs in the braid-reinforced tube, the diameter ratio has already decreased to nearly 0.6, while the coil-reinforced tube maintains a value closer to 0.8 before kinking. The ability of a sheath to maintain a substantially circular cross-section is an important characteristic of a sheath if an interventional device, such as a stent, is to be passed through the sheath for delivery into a body passageway. Even after the ratio has begun to decrease, the ability to maintain a high minor-to-major diameter ratio through a larger bending angle provides greater opportunity for a medical practitioner to successfully deliver an interventional device through the sheath to a desired location in a body passageway.

Based upon the computer simulation FEA examinations performed by ABAQUS, it is clear that the use of a coil reinforcement in an introducer sheath provides significant advantages over a sheath that uses a braid reinforcement, or a sheath that is unreinforced. For example, the coil-reinforced sheath has a preferential stiffening effect in the circumferential direction as opposed to the axial direction. Since cross-sectional kinking is related to the ratio of circumferential stiffness (that opposes kinking) to the axial compressive stress (that causes kinking), a preferential increase of circumferential stiffness is desirable. Stated another way, the resistance of the cross section to kinking is increased by the coil without a corresponding increase in the compressive stress at the bent inner diameter of the sheath during bending – low axial compression increase with greater circumferential stiffness increase leads to increased kink resistance.

In a braid-reinforced sheath, the circumferential stiffening is accompanied by a

corresponding increase in axial compressive stress. Thus, while the braid-reinforced sheath does provide improved kink resistance compared to the un-reinforced sheath, the kink resistance is limited when compared to that of the coil-reinforced sheath. Secondly, a coil, at any helix angle, always has base material between its coils. This can be noted by visual inspection of a coil-reinforced sheath. In effect, the only way for load to be transmitted axially in a coil is through the polymeric material of the tubes that fills the space between the turns in the coil. The same is not true in a braid where the crossing braid wires provide a load path axially down the sheath. This is why the braid produces additional axial compressive stress whereas the coil does not. Barnes Declaration, paragraphs 20, 21.

As stated in the Declaration of Dr. Roubin, a preeminent medical doctor and the Chairman of the Department of Interventional Radiology at Lennox Hill Hospital in New York, guiding catheters (introducer sheaths) in use prior to about 1994 generally were unreinforced or comprised a layered structure having a braided reinforcement. Use of such guiding catheters was problematic, as it was difficult to advance them through challenging peripheral vascular anatomy such as tortuous iliac arteries, contralateral iliofemoral arteries, and carotid arteries. Roubin Declaration, paragraph 3.

Sometime around 1994 Dr. Roubin began using a guiding sheath developed by Cook. This guiding sheath differed from previous braid-reinforced guiding catheters and sheaths, and unreinforced catheters and sheaths, in that it comprised a layered structure having a low friction inner layer, a coiled reinforcement fitted around the inner layer, and an outer nylon layer positioned around the coil and inner layer and connected to the inner layer through the turns of the coil. In Dr. Roubin's experience, this coiled-reinforced sheath had greater flexibility and kink-resistance than the braid-reinforced device, which beneficial property proved essential in negotiating tortuous peripheral vasculature. As an example of the superior results obtainable with use of the coil-reinforced catheter, Dr. Roubin stated that, in his experience, neither an unreinforced sheath nor a braid-reinforced sheath could normally be introduced through tortuous anatomy such as the path from the aortic arch into the inominate artery and into the distal right common carotid artery. The inability of a braid to traverse this tortuous anatomy was likely due to the fact, that unlike a coil, a braid does not have sufficient flexibility and kink-resistance to

traverse the small radius bends encountered along this path. Roubin Declaration, paragraphs 5, 6.

According to Dr. Roubin, in his experience the aforementioned coil-reinforced sheath is superior to both a braid-reinforced sheath and to an unreinforced sheath, because the coil-reinforced sheath has sufficient flexibility and kink resistance to traverse small radius bends in the vasculature, such as the bends from the aortic arch into the inominate artery and into the distal right common carotid. This can be done with a coil-reinforced sheath with little or no difficulty in most patients. As a result, the physician is able to treat conditions that may arise in difficult-to-reach areas of the vasculature utilizing guiding catheter and wire guide technology, that otherwise would require much more invasive techniques, if they could be performed at all.

The primary Horrigan reference teaches a guiding catheter for use in PTCA. According to the patent specification, it is an important characteristic of such catheters that they have sufficient stiffness to be pushed through vessels, as well as sufficient rigidity to provide a high degree of torsional control. Col. 1, lines 15-21. In Horrigan, an inner PTFE liner is reinforced by fusing a wire braid along the outer diameter of the PTFE liner. The braid terminates a few millimeters proximal to the distal end of the liner. Col. 4, lines 18-25.

It is well-known that a desirable feature of an introducer sheath is that it be thin-walled. Nevertheless, Horrigan chose to utilize a wire braid fused to the inner liner as a reinforcement means, rather than a wire coil as in the present invention. The very nature of a braided wire indicates that the braid includes wire cross-over points, which add to the wall diameter. On the other hand, a coil structure does not include cross over points. In addition, it is well known in the art that the use of a wire braid reinforcement provides favorable torsional control when compared to a wire coil (torsional control being a stated objective of Horrigan). However, it is also known that the kink resistance of a braided reinforcement is inferior to that of a wire coil.

Although Horrigan refers to his design on one occasion as providing kink resistance (a point that was noted by the Examiner in the instant Office Action), this comment was not provided to compare the kink resistance provided by the braided Horrigan device to the kink resistance of a device that included a coil reinforcement, nor to extol the capability of the Horrigan device to traverse tortuous pathways. Rather, the point is merely made therein that

some kink resistance may be obtained by a certain braided structure under certain circumstances. In fact, the patent neither discusses this asserted "benefit" any further, nor provides any factual support for the underlying contention. As shown in the attached exhibits to the Barnes Declaration, a braid-reinforced sheath may indeed exhibit some kink resistance under certain circumstances. However, the kink resistance of a coil reinforcement is much greater than that of a braid reinforcement. Furthermore, this showing of superior kink resistance in a coil-reinforced sheath compared to a braid-reinforced sheath represents much more than an insignificant academic exercise. Rather, the showing illustrates the ability of a coil-reinforced sheath to be successfully utilized for an intended purpose in a potentially life and death medical procedure, under circumstances when a braid-reinforced sheath in insufficient. This is a real-world difference, and can obviously have extreme repercussions to those patients whose treatment requires access to tortuous areas of the vasculature.

In support of her rejections, the Examiner stated in the Office Action that she "disagrees with the Applicant's previously-stated position that a braid-reinforced sheath is prone to kinking while a coil-reinforced sheath is effective for resisting kinking." OA, page 6, lines 28-29. In light of the Declarations of David Barnes and Dr. Roubin, and the Remarks provided herein, the Applicant respectfully requests the Examiner to reconsider this position.

In the final Office Action, the Examiner took issue with evidence presented by the Applicant in a previous reply, and stated that the comparison between a braid reinforcement and a coil reinforcement must compare the claimed subject matter with the closest prior art (i.e., Horrigan) to be effective to rebut a prima facie case of obviousness. Applicant respectfully submits that such a comparison has now been made.

As stated, the present invention utilizes a coil (rather than a braid), to provide enhanced kink resistance to a sheath. Additionally, as stated in a previous reply, a coil is also advantageous for permitting the sheath to be constructed to have a smaller wall diameter, and to reduce the manufacturing cost of the sheath. The Horrigan reference neither teaches nor suggests an optimal manner of achieving such advantages, and in fact, by its use of a reinforcement braid, teaches away from such advantages. Park teaches a complex solution to the problem of access through increasingly small vessels that is very different than the present

invention. Park also does not appear to recognize the problems relating to kinking that may be caused by using a braid reinforcement. Neither of these references, either individually or in combination, achieves the simple solution to the problems of kink resistance, minimizing the outer diameter, and maintaining as little expense as possible, that are achieved in the inventive sheath. Neither of the cited references provides any awareness of the significant problems involved in traversing tortuous passages that are solved by the use of a coiled sheath, nor do they teach or suggest an effective solution to these problems. Thus, Applicant respectfully submits that the combination of references cited by the Examiner in support of these rejections is insufficient to establish a prima facie case of obviousness of a coil-reinforced sheath of the type claimed herein.

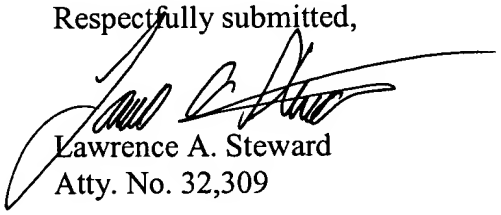
Therefore, for all of the foregoing reasons, Appellant respectfully submits that claims 1-2, 4-5, 10-13 and 15-20, as amended, are not obvious in view of the cited combination.

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Parker (US 5,380,384). Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju et al (US 5,599,325). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of MacDonald et al (US 6,210,396).

According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. MacDonald was cited for its teaching of an outer tube comprising first and second tube sections of different colors. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1.

Based upon the foregoing, Applicant respectfully submits that all claims 1-21 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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